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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,533

01/20/2005

Olivier Loiseleur

ON/4-32331A

7484

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02/18/2009

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/502,533	<b>Applicant(s)</b> LOISELEUR ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8, 12-14 and 16 is/are rejected.
- 7) ☒ Claim(s) 5, 7, 9-11, and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 7/26/04 wherein claims 1, 3-9, and 12-14 were amended.

**Note:** Claims 1-16 are pending.

## **APPLICANT'S INVENTION**

2. Applicant's invention is directed to a conjugate as set forth in independent claim 1 and methods thereof.

## **112 SECOND PARAGRAPH REJECTIONS**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2: The claim is ambiguous because it is unclear if Applicant intended to add another structure or not. Specifically, in lines 1-2, it is set forth that the conjugate has a structure selected from the group of structures (I) to (V); however, there is no structure (V) disclosed in the claim.

Claim 13: The claim is ambiguous because the sentence is incomplete. Thus, it is unclear what is being claimed.

Claim 16: The claim as written is ambiguous because it is unclear what other symbols and radicals Applicant is claiming in claim 16 (see lines 5-6 and 13). In addition, the claim is ambiguous because of the phrase 'with a bond that can be

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hydrolyzed under reaction conditions that do not result in the hydrolysis of peptide bonds' (see claims 11-12). Thus, it is unclear what conditions and other reactions Applicant is referring to that are compatible with the instant invention.

### 103 REJECTION

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 1, 3, 4, 6, 8, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al (Helvetica Chimica Acta, 1998, Vol. 81, pages 2141-2156).

**Abele et al** disclose beta homolysine containing peptides. The peptides contain two, three, and seven side chains of lysine (see entire document, especially, abstract). In addition, Abele et al disclose that a compound having a polylysine section conjugated to an anionic component such as DNA (pages 2141 and 2143, bridging paragraph). Also, Abele et al disclose Compound 1 wherein the peptide contains seven homolysine residues (page 2153, third complete paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a conjugate comprising at least four beta homolysine residues that is conjugated to a compound that is to be delivered across a biological barrier because Abele et al discloses that peptides containing multiple homolysine residues may be conjugated to DNA. Thus, both Applicant and Abele et al disclose a conjugate comprising at least four beta homolysine residues.

#### **CLAIM OBJECTIONS**

9. Claims 5, 7, 9-11, and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Note:** The limitations present in the dependent claims are neither disclosed nor suggested by the prior art of record.

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### **SPECIFICATION**

10. The disclosure is objected to because of the following informalities: Applicant is respectfully requested to insert the continuing data into the first paragraph of the specification

Appropriate correction is required.

### **APPLICATION DATA SHEET**

11. Applicant is respectfully requested to review the application data sheet. In particular, the application data sheet is not consistent with the declaration/oath. Specifically, the invention listed on the application data sheet is not one of the inventors listed on the declaration/oath. Thus, Applicant is respectfully requested to make the appropriate corrections in order to have consistency throughout the claims.

### **COMMENT/NOTES**

12. Applicant is respectfully requested to submit a copy of the documents and an information disclosure statement of the document used in the international search.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/  
Primary Examiner  
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February 16, 2009